PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/006296	30.04.2004	02.05.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/50, A61K49/22

Applicant
CANON KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/006296

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-20
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 97/43005 A

D2: EP 1 275 378 A

D3: Gómez-Lopera SA et al. (2001) J. Colloid Interface Sci. 240: 40-47

D4: Häfeli UO et al. (1995) Nucl. Med. Biol. 22: 147-155

Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-20 is not new in the sense of Article 33(2) PCT.

1 - Document D1 (page 9, line 21 - page 10, line 23; page 14, line 14 - page 16, line 3; example; claims) discloses a method of treating diseased tissue with magnetic material. In a preferred embodiment, the magnetic material is delivered in the form of microcapsules, having the magnetic material bound in a matrix material, e.g. Biopol (copolymer of hydroxybutyric acid and hydroxyvaleric acid). The microcapsules could also contain a cytotoxic material. In the example, the microcapsules are prepared by mixing γFe_2O_3 particles in a Biopol solution in dichloromethane. This mixture is dropped in an aqueous PVA solution, followed by evaporation of the dichloromethane. Consequently, claims 1-4, 6-8, 11, 12 and 20 are considered to lack novelty over D1.

2 - Document D2 (claims) discloses particles comprising an external phase containing a polyhydroxyalkanoate, and an internal phase, and methods for making these particles. In the description, § 288, the inclusion of magnetite is suggested, which is a magnetic compound. Hence, claims 1-19 lack novelty over D2.

3 - Document D3 (abstract; page 41, right-hand column, last par.) discloses particles comprising a magnetite nucleus and a coating of polylactide, which can be seen as a polyhydroxyalkanoate. The particles are prepared by a W/O/W emulsion solvent evaporation process, whereby the inner aqueous phase is a suspension of magnetite particles. Their use as drug delivery vehicles is suggested. The subject-matter of claims 1, 2, 4, 6-12 and 20 therefore lacks novelty in view of D3.

4 - Document D4 (abstract; page 148, par. bridging columns) discloses polylactide microspheres comprising magnetite and ^{90}Y. The particles are prepared by a O/W emulsion solvent evaporation method, whereby the oil phase comprises magnetite particles. ^{90}Y is considered to be a "pharmaceutical component". D4 thus precludes the novelty of claims 1, 2, 6-8, 11, 12 and 20.

Inventive Step

Lacking novelty, claims 1-20 cannot be regarded as inventive (Article 33(3) PCT).

Industrial applicability

Claims 1-20 comply with Article 33(4) PCT.